

REMARKS

Applicant and the undersigned would like to thank the Examiner for Examiner's efforts in the examination of this application.

I. Drawings

The Examiner has objected to the drawings of the present application for not showing all of the features of the claimed invention. Specifically, the Examiner has objected to the drawings for not showing every claimed feature. In particular, the Examiner has suggested that all of the features must be shown in the figures or removed from the claims: "1) a surgical drain having a fiber optic with a branched distal end branches from the conduit and a plurality of drain holes and 2) a surgical drain having a fiber optic with a branched distal end branches and further comprising third and fourth optical fibers"

However, "a surgical drain having a fiber optic with a branched distal end [that] branches from the conduit and a plurality of drain holes" is shown in figures 4A, 4B, 1B and 3D-3F of the application. Figures 4A and 4B, show a fiber optic 48 (which is the transmitter in this embodiment) that is branched from the conduit, and a fiber optic 12 (which is the receiver). While figures 4A and 4B provide the side views of the surgical drain 10 (and since it is a side view the drain holes are not shown), figures 1B and 3D-3F show the top view of the conduit, including the drain holes 34.

With respect to the Examiner's second item above ("a surgical drain having a fiber optic with a branched distal end branches and further comprising third and fourth optical fibers"), once again a surgical drain 10 having a fiber optic with a branched distal end 48 is shown in figure 4A. While the further limitations of the surgical drain comprising a third and a fourth optical fibers of the claims may not have been shown at this time, they are within the knowledge of one with ordinary skill in the art based on other embodiments such as in figures 3D and 3E, which teach a plurality of transmitters and receivers, such as the third and fourth optical fibers above. Nevertheless, the Applicant has cancelled claims 10 and 11, corresponding to an embodiment having a

third and fourth optical fiber. The Applicant's cancellation of these claims is entirely without prejudice to the Applicant's right to pursue claim coverage of an equivalent scope at a later time.

II. Specification

The Examiner objected to language in the abstract of the disclosure of the specification. The particular language of the abstract has been amended as suggested by the Examiner.

III. Claim Rejections under 35 USC § 102

The Examiner rejected claims 16-19 under 35 U.S.C § 102(b) as being anticipated by Johnson (US 3,866,599). Applicants have cancelled claims 16-19 without prejudice. Applicants have chosen not to address the rejections based on prior art at this time but affirmatively and explicitly reserve the right to do so at later time. Accordingly, Applicants have not conceded the merits of the Examiner's rejections of these claims, nor has Applicants surrendered any of the scope of the claim coverage afforded by these claims based on the rejections set forth by the Examiner in the current office action.

IV. Claim Rejections, 35 USC § 103

The Examiner has rejected claims 1-6 and 8-14 over Johnson (3,866,599) in view of Polanyi (US 3,674,013). Claim 1 has been amended as follows:

1. A-An implantable surgical drain for draining fluid from a patient's body and sensing at least one physiological property of tissue by sensing energy that has been transmitted through and emitted from the tissue, comprising: an elongated conduit, having an outer surface, configured to be implanted in a patient's body and to drain fluid from tissue of the body while the conduit is placed adjacent to the tissue a patient's

body; a first optical fiber having a first optical fiber distal end, wherein the distal end branches away from the ~~conduit~~ conduit's outer surface and is configured for insertion in the tissue inside the patient's body, proximate to ~~the conduit wherein the optical fiber distal end is~~ and configured to deliver energy to the tissue, wherein the delivered energy passes through, and is emitted from, the tissue; and a second optical fiber different than the first optical fiber having a second optical fiber distal end configured to receive the energy emitted from the tissue.

The above amendment to Claim 1 is meant to emphasize the novel and non-obvious features of the claimed invention. No new matter has been added.

The Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met (MPEP § 2143). First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings (MPEP § 2143.01). Second, there must be a reasonable expectation of success (MPEP § 2143.02). Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations (MPEP § 2143.03).

As argued in the response to the previous office action, Johnson does not disclose the present surgical drain having an optical fiber, wherein the optical fiber distal end branches away from the conduit and is configured for insertion into tissue. The Examiner on page 6 of the office action recites that "Polanyl teaches the fibers that are directed at an angle to one side of the catheter wall so that the optical fiber remains spaced from the body organs." Polanyl's optical fiber distal ends do not branch away from the catheter. Claim 1 of the present invention requires an optical fiber distal end branches away from the conduit. Polanyl's catheter has fiber optic distal ends that are angled within the catheter. As described in the specification, the optical fiber that branches from the conduit, as illustrated in figures 4A and 4B of the present application, is configured for a transmittance measurement. In claim 1 of the present application,

the target tissue to be analyzed lies between the transmitting and the receiving optical fibers so that the transmitted light would pass through the target before being received (for example, see figures 4A and 4B, and accompanying text, of the present application). The distal end of the optical fiber branching away from the conduit allows insertion of the optical fiber into the tissue, so that the energy transmitted by the first optical fiber can pass through the tissue to the receiving optical fiber. Johnson does not disclose such a configuration; and Polanyl does not disclose the distal end of an optical fiber branching from the conduit for insertion into tissue.

Rather, Johnson and/or Polanyl disclose that the optical fibers embedded within an intravascular catheter *irradiate blood and collect the reflected light* from the blood to determine oxygenation saturation of the blood. In Johnson's reflection arrangement, both the transmitting and receiving fibers are on the same side facing the target (namely, the blood in the tip-recess of the catheter) so that the light emitted by one fiber is reflected back to be collected by another fiber. Therefore, the *prima facie* case has not been established with respect to claim 1 above since neither of the prior art teach "optical fiber distal end branches away from the conduit" and therefore claim 1 is allowable over the cited references.

Claims 2-6, 8, 9 and 12-14 depend directly or indirectly from claim 1 and are thus themselves allowable for the same reasons.

The Examiner also rejected claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Johnson in view of Polanyl and further in view of Russo et al. (US 4,317,452). The Applicant respectfully traverses the rejection. To establish a *prima facie* case of obviousness, three basic criteria must be met (MPEP § 2143). First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings (MPEP § 2143.01). Second, there must be a reasonable expectation of success (MPEP § 2143.02). Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations (MPEP § 2143.03).

First, there is no suggestion or motivation to combine or modify the prior art cited by the Examiner. One would not be motivated, as suggested by the Examiner, to “provide Johnson in view of Polanyl with a plurality of holes in the tube wall to affect the manner in which fluid passes/flows into the tube. Thus it would not have been obvious to one of ordinary skill in the art to provide the intravascular catheter of Johnson in view of Polanyl with a plurality of holes, as taught by Russo et al., since doing so would allow for a vital body fluid (i.e., blood) to be drained from a vessel along a substantial length of the tube and/or from a substantial portion of the vessel.” The Examiner fails to show all the limitations of the claim as discussed with respect to claim 1 above and motivation to combine. It is unclear why would one of ordinary skill in the art would be motivated to combine drain holes of Russo with Johnson and Polanyl to drain fluid from a body cavity, since the Examiner asserts that Johnson already performs the function of draining fluid from the body. If Johnson teaches draining fluid with respect to the present claim 1, as asserted by the Examiner, then one of ordinary skill in the art would not be motivated to modify Johnson’s catheter with Russo’s drain holes. Russo et al. also does not teach or suggest an optical fiber distal end branches away from the conduit of claim 7. Therefore, two key criteria for establishing a *prima facie* case have not been met: 1) prior art has to have all the elements of the claim and 2) motivation to combine. Thus, claim 7 is allowable in view of the prior art.

V. CONCLUSION

Applicant respectfully submits that the above amendments place this application in a condition for allowance, which Applicant respectfully solicits. The Applicant and the undersigned would like to again thank the Examiner for the Examiner’s efforts in the examination of this application and for reconsideration of the claims as amended in light of the arguments presented. If the further prosecution of the application can be facilitated through interview between the Examiner and the undersigned, the Examiner is requested to telephone the undersigned at the Examiner’s convenience.

Serial No. 10/775,670

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account.

Respectfully submitted,
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